

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

HEALIX INFUSION THERAPY, INC.,

Plaintiff,

V.

DEPUY MITEK, INC.,

Defendant

§
§
§
§
§
§
§
§
§
§
§

CIVIL ACTION NO. 11-CV-4118

PLAINTIFF'S ORIGINAL COMPLAINT

NOW COMES Plaintiff Healix Infusion Therapy, Inc. and files this, its Original Complaint against Defendant Depuy Mitek, Inc. and would show the Court as follows:

PARTIES

1. Plaintiff Healix Infusion Therapy, Inc. ("Healix") is a corporation organized under the laws of the State of Texas, with its corporate office located at 14140 Southwest Freeway, Fourth Floor, Sugar Land, Texas 77478.

2. Defendant DePuy Mitek, Inc. ("Depuy Mitek") is a corporation organized under the laws of the State of Massachusetts, with its corporate office located at 325 Paramount Drive, Raynham, Massachusetts 02767.

JURISDICTION AND VENUE

3. This is an action for breach of a settlement agreement. Jurisdiction is premised upon 28 U.S.C. §1332 because the Parties are diverse and the matter in controversy exceeds \$75,000.00.

4. The Court has personal jurisdiction over Depuy Mitek and venue is proper pursuant to 28 U.S.C. § 1391 based on the acts alleged herein have been, in whole or in part, conceived, carried out and made effective within the District and in interstate commerce.

FACTS COMMON TO ALL COUNTS

5. Healix is the owner of the HEALIX® trademarks as reflected by United States Federal Trademark Registration Nos. 2,258,592; 3,098,781; 3,098,782 and 3,101,469. The HEALIX trademark has been used in the healthcare industry since 1989 and is valid, subsisting, and in full force and effect.

6. In 2008, Healix filed suit against Depuy Mitek for trademark infringement and other causes of action to prevent it from infringing on its mark. *See* Case No. 4:08-cv-03706; *Healix Infusion Therapy, Inc. v. Johnson & Johnson and Depuy Mitek*; United States District Court for the Southern District of Texas. Specifically, Healix objected to Depuy Mitek's use of HEALIX in the healthcare industry.

7. During the course of litigation, the Parties entered into a settlement agreement (the "Settlement Agreement") on February 17, 2009. ***See Exhibit "A"***. The relevant terms of the Settlement Agreement were:

2.2 Mitek agrees that it will use not use the mark HEALIX, except in connection with sutures, suture anchors, surgical instrumentation directly related to suture anchors, or other surgical products used for repair of rotator cuff, shoulder instability, meniscus or anterior cruciate ligament injuries. For such products, Healix consents to the use by Mitek of marks which combine HEALIX with another term including but not limited to "HEALIX PEEK", "HEALIX BR", "HEALIX Awl" and "HEALIX TI".

2.3 Mitek shall not use the designation HEALIX as a stand-alone mark, but may use terminology such as "Healix family of anchors" or alternative terminology which in the context in which it appears designates a reference to or use with more than one Mitek suture anchor product bearing the Healix name at a time (i.e. both HEALIX BR and HEALIX TI), and further that "HEALIX". by itself is not claimed as a separate trademark of Mitek.

2.4 Notwithstanding any other provision in this Agreement, Mitek may continue to use any marketing, labeling or other materials displaying “HEALIX” in the same manner in which it has been used prior to this Agreement for a period of six months from the Effective Date, and shall not be required to change any historical or permanent records displaying HEALIX.

9. Breaches/Disputes. In the event of any dispute, controversy, breach, difference or claim relating to or arising out of this Agreement (a “Controversy”), the Parties hereto agree to first attempt in good faith to settle the Controversy through negotiations for a period of sixty (60) days after such Controversy arises, before bringing any action for breach of this Agreement. Such Controversy shall be considered to arise only after receipt by the offending party of a written notice identifying the nature of such Controversy. In the event that the Controversy is not resolved through such negotiations then the exclusive remedies to settle the Controversy shall be a trademark opposition in the Patent and Trademark Office and/or a civil action to seek specific performance (or, if the parties agree, through binding arbitration action).

8. Healix entered into the Settlement Agreement and released its infringement claim against Depuy Mitek in exchange for the peaceable enjoyment of its trademark, without conduct that would infringe upon it.

9. Despite entering into the Settlement Agreement, Healix later learned that Depuy Mitek had failed to comply with various sections through their ongoing use of the HEALIX mark.

10. On June 1, 2011, Healix notified Depuy Mitek that it was in violation of section 2.3 of the Settlement Agreement based on its use of HEALIX™ Anchors, HEALIX™ BR Anchor and HEALIX™ Awl.

11. On September 4, 2011, Healix notified Depuy Mitek that it was once again in violation of the Settlement Agreement based upon multiple violations that were not previously discovered. These violations included third parties under Depuy Mitek’s control using the prohibited marks for its benefit, as well as Depuy Mitek using “Engineered with HEALIX Dual Thread Technology™” in its marketing brochures and distributing the same through third parties in the District. **See Exhibit “B”.**

12. In response to both notifications, Depuy Mitek represented that it had corrected the majority of the violations, yet claimed that its use of “Engineered with HEALIX Dual Thread Technology™” was not in violation of the Settlement Agreement. **See Exhibit “C”.**

13. While Depuy Mitek corrected a portion of the violations, others were not corrected. As of the filing of this Complaint, Healix has discovered additional use of the HEALIX mark by Depuy Mitek as well as by third parties. **See Exhibit “D”.**

14. Depuy Mitek’s use of “Engineered with HEALIX Dual Thread Technology™” fails to comply with the terms of the Settlement Agreement as does its other, ongoing use of the HEALIX mark. Accordingly, Depuy Mitek has violated sections 2.2, 2.3 and 2.4 of the Settlement Agreement. The Parties have attempted to resolve this dispute without the necessity of litigation, but have been unable to do so.

15. Healix has performed all conditions precedent as required by contract and law.

COUNT ONE

BREACH OF CONTRACT

16. Healix incorporates all of the matters above as if fully set forth herein.

17. The Settlement Agreement is a valid contract between Healix and Depuy Mitek with an effective date of February 17, 2009.

18. Healix fully performed its obligations under the terms of the Settlement Agreement.

19. Depuy Mitek has failed to comply with the terms of the Settlement Agreement through its ongoing use of the HEALIX mark, by its failure to assume responsibility for those under its control that use the HEALIX mark and its refusal to refrain from further use of “Engineered with HEALIX Dual Thread Technology™”.

20. As a result, Healix has been irreparably damaged by Depuy Mitek’s continued

unauthorized use and corresponding dilution of the HEALIX mark, as well as the denial of its exclusive use of the HEALIX mark for which it had bargained for in the Settlement Agreement.

21. As a result of the Settlement Agreement being breached, Healix's injury is irreparable and the legal remedy of damages is inadequate due to the continuing injury to the goodwill of its mark. Specific performance through a permanent injunction is therefore appropriate to enforce Depuy Mitek's contractual promise not to use Healix's mark.¹

COUNT TWO

ATTORNEY'S FEES

22. Healix incorporates all of the matters above as if fully set forth herein.

23. Pursuant to Section 38.001 of the Texas Civil Practices and Remedies Code, Healix is entitled to recover reasonable attorney's fees from Depuy Mitek because it presented its claim and demand for attorney's fees, yet to date, these issues have gone unresolved.

PRAYER FOR RELIEF

WHEREFORE PREMISES CONSIDERED, Healix prays that:

(a) Depuy Mitek, its officers, employees, agents, distributors, servants, attorneys, successors and assigns, related companies and all those persons in active concert or participation with them, be permanently enjoined and restrained from using the HEALIX mark beyond the scope of the Settlement Agreement, including but not limited to the use of "Engineered with HEALIX Dual Thread Technology™" and be required to destroy all marketing materials bearing the phrase "Engineered with HEALIX Dual Thread Technology™" as well as take further action to remove all violations of the Settlement Agreement appearing on third party websites, followed by showing proof of its efforts to the Court;

¹ For purposes of specific performance, Healix has shown: (1) compliance with the Settlement Agreement, including tender of performance; and (2) the readiness, willingness, and ability to perform at relevant times.

(b) it recovers its attorney's fees pursuant to Section 38.001 of the Texas Civil Practices and Remedies Code; and

(c) it recovers such other relief as the Court may deem appropriate.

Respectfully submitted,

By: 

Scott Weiss, Attorney-in-Charge
Texas Bar No. 24042134
14140 Southwest Freeway, Ste. 400
Sugar Land, Texas 77478
281-295-4122
832-201-0687 (Fax)
sweiss@healix.net

**ATTORNEYS FOR PLAINTIFF
HEALIX INFUSION THERAPY, INC.**

EXHIBIT “A”

CONFIDENTIAL CONCURRENT USE AGREEMENT

This Confidential Concurrent Use Agreement (this "Agreement"), effective February 17, 2009, is between DePuy Mitek, Inc., (and all subsidiaries thereof) having a principal place of business at 325 Paramount Drive, Raynham, Massachusetts 02767 ("Mitek") and Healix Inc. and Healix Infusion Therapy, Inc., (and all subsidiaries thereof), both Texas corporations having a principal place of business at 14140 Southwest Freeway, Sugar Land, Texas 77478 ("Healix"). In consideration of the mutual promises in this Agreement, the parties agree as follows.

1. Recitals:

1.1 Healix owns the following trademark registrations that are for the mark HEALIX: U.S. trademark registrations 2,258,592; 3,098,781; 3,098,782; and 3,101,469; and Texas trademark registrations 5,520,517 and 5,543,517 (the "Healix Registrations").

1.2 Mitek has been using the designation HEALIX in connection with the marketing of suture anchors, including the logos as shown in Exhibit A-1 and A-2 hereto (the "Mitek Mark").

1.3 Healix filed civil action no. 4:08-cv-3706 in the Southern District of Texas alleging trademark infringement, trademark dilution and unfair competition ("the Civil Action").

1.4 The parties believe that the limited use of HEALIX Mitek set forth herein is such that, in view of Healix's prior rights to use the mark HEALIX, it is not likely to cause confusion, to cause mistake or to deceive consumers.

1.5 Healix and Mitek desire to resolve any and all disputes relating to the Civil Action and the mark HEALIX.

2. Usage of Mark:

2.1 Mitek shall not use HEALIX as a company name or the name of any business operating division.

2.2 Mitek agrees that it will use not use the mark HEALIX, except in connection with sutures, suture anchors, surgical instrumentation directly related to suture anchors, or other surgical products used for repair of rotator cuff, shoulder instability, meniscus or anterior cruciate ligament injuries. For such products, Healix consents to the use by Mitek of marks which combine HEALIX with another term including but not limited to "HEALIX PEEK", "HEALIX BR", "HEALIX Awl" and "HEALIX TT".

2.3 Mitek shall not use the designation HEALIX as a stand-alone mark, but may use terminology such as "Healix family of anchors" or alternative terminology which in the context in which it appears designates a reference to or use with more than one Mitek suture anchor product bearing the Healix name at a time (i.e. both HEALIX BR and HEALIX TI), and further that "HEALIX" by itself is not claimed as a separate trademark of Mitek.

2.4 Notwithstanding any other provision in this Agreement, Mitek may continue to use any marketing, labeling or other materials displaying "HEALIX" in the same manner in which it has been used prior to this Agreement for a period of six months from the Effective

Date, and shall not be required to change any historical or permanent records displaying HEALIX.

2.5 Healix shall not use the designation HEALIX in connection with suture anchors or other surgical products used for repair of rotator cuff, shoulder instability, meniscus or anterior cruciate ligament injuries.

3. Dismissal of the Civil Action: Within 10 business days of the effective date of this Agreement, the parties shall file a Stipulation of Dismissal of the civil action in the form attached as Exhibit 1.

4. Registrations, Oppositions and Cancellations:

4.1 Mitek shall not oppose or petition for cancellation any Healix application or registration for the mark HEALIX provided that the application or registration is not directly related to suture anchors or other surgical products used for repair of rotator cuff, shoulder instability, meniscus or anterior cruciate ligament injuries.

4.2 Except as provided herein, Mitek shall not seek to register as a mark in the U.S. HEALIX in any form other than the logo shown in Exhibit A-1. Healix consents to and shall not oppose or petition to cancel the application or registration for the logo shown in Exhibit A-1. In the event that Mitek desires to register in the U.S. a different mark containing HEALIX, (1) said mark must not be a form that uses HEALIX in a more prominent manner than as shown in Exhibit A-1, (2) Mitek shall abandon the U.S. registration of the mark in Exhibit A-1 upon registration of said different mark, (3) Mitek shall obtain Healix's approval of the design element, which approval shall not be unreasonably withheld or delayed.

5. Costs and Attorneys Fees: Each party shall be responsible for its own costs and attorney fees arising in connection with the Civil Action.

6. Abandonment: If Healix abandons its use of all of the marks in the Healix Registrations, or if Mitek abandons its use of the Mitek Mark (as defined by the Lanham Act), that party's rights under this Agreement shall be lost and the other party may thereafter use its mark or marks in all proper ways, unrestrained by the terms of this Agreement, and may thereafter apply for and obtain a federal registration of its mark unrestricted by this Agreement.

7. No Admission. This Agreement is made for the purpose of settling the above-referenced disputes and is not an admission of liability by any party.

8. Releases:

8.1 Healix, for itself and for its successors and assigns, releases and forever discharges Mitek and its officers, directors, employees and agents, from any and all claims, causes of action, rights, allegations, liabilities or damages whatsoever relating to the mark HEALIX that exist as of the date of this Agreement.

8.2 Mitek, for itself and for its successors and assigns, releases and forever discharges Healix and their officers, directors, employees and agents, from any and all claims, causes of action, rights, allegations, liabilities or damages whatsoever relating to the mark HEALIX that exist as of the date of this Agreement.

9. **Breaches/Disputes.** In the event of any dispute, controversy, breach, difference or claim relating to or arising out of this Agreement (a "Controversy"), the Parties hereto agree to first attempt in good faith to settle the Controversy through negotiations for a period of sixty (60) days after such Controversy arises, before bringing any action for breach of this Agreement. Such Controversy shall be considered to arise only after receipt by the offending party of a written notice identifying the nature of such Controversy. In the event that the Controversy is not resolved through such negotiations then the exclusive remedies to settle the Controversy shall be a trademark opposition in the Patent and Trademark Office and/or a civil action to seek specific performance (or, if the parties agree, through binding arbitration action).

10. **Integration:** This Agreement constitutes the entire agreement between the parties regarding their rights throughout the United States of America, and may not be modified or amended, except in a writing specifically referring to this Agreement and executed by both parties. The parties acknowledge that Mitek and entities related to Mitek may have rights in the mark HEALIX outside of the United States and this agreement is not intended to affect materials intended for distribution primarily outside of the United States, but which may be accessible from locations the United States or have some incidental distribution in the United States.

11. **Confidentiality.** The Parties agree to keep confidential the terms of this Agreement. The Parties further agree that they will not disclose, directly or indirectly, any such information to any person or entity except (a) as necessary to enforce or perform this Agreement or (b) as required by a subpoena or other court or administrative order requiring disclosure of such information.

HEALIX INFUSION THERAPY, INC.:

By: 

Print Name: Thomas F. Schwartz

Title: Vice President

Date: 11 Feb 09

HEALIX, INC.:

By: 

Print Name: Thomas F. Schwartz

Title: Vice President

Date: 11 Feb 09

DEPUY MITEK, INC.:

By: 

Print Name: Michael McGreen

Title: Vice President, Sales/Mkt

Date: 2/17/09

Exhibit A-1



Alternative Form of ☐
Exhibit A-1

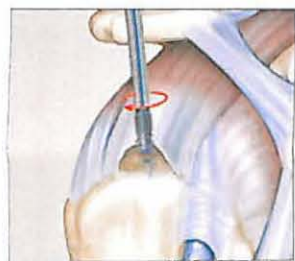


EXHIBIT “B”

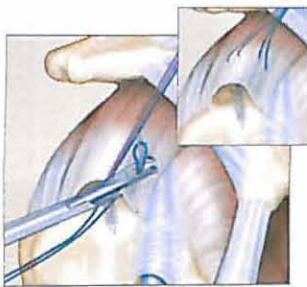
CUFFLOK™ Surgical Technique³**Pascal Boileau M.D.**Department of Orthopaedic Surgery, Hôpital de L'Arche,
University of Nice, Nice, France**Ordering Information****Engineered with HEALIX Dual Thread Technology™**

HEALIX Ti product breadth provides versatility to address the demands from a wide variety of techniques & tear configurations

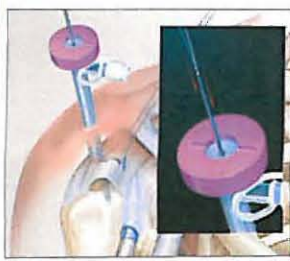
- Sizes (4.5mm, 5.5mm, 6.5mm)
- Arthroscopic and Needle versions
- Comes preloaded with 2 or 3 strands of ORTHOCORD® Suture



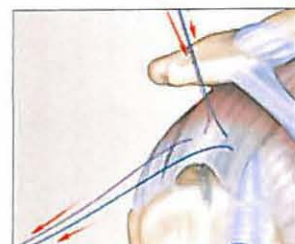
- 1 Insert HEALIX Ti™ Dual Threaded Suture Anchor adjacent to the articular margin on the medial tuberosity.



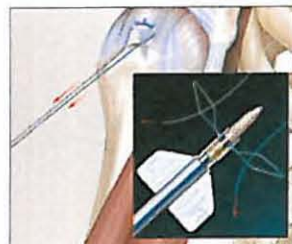
- 2 Group like colored suture limbs together and pass either anteriorly or posteriorly with EXPRESSEW® II Flexible Suture Passer.



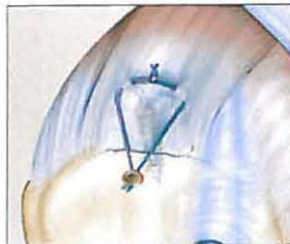
- 3 Grasp and remove inner suture limbs (one purple and one blue) together and tie a secure knot outside the shoulder.



- 4 Pull opposite limbs to advance knot into the subacromial space securing the medial aspect in a mattress fashion.

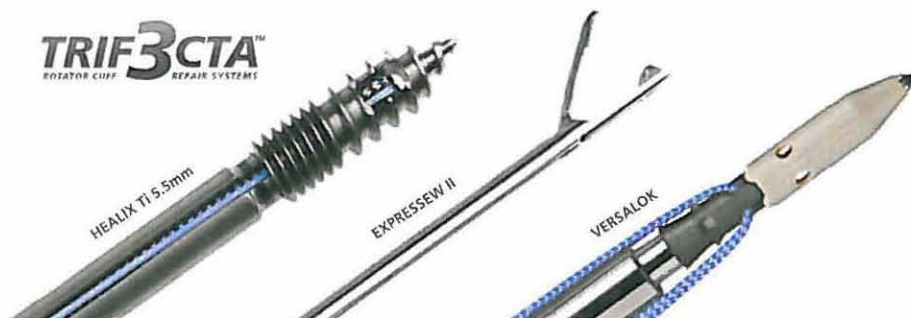


- 5 Place limbs into a VERSALOK® Suture Anchor, insert VERSALOK® Anchor into the bone and load deployment gun. Once sutures are tensioned deploy anchor.



- 6 Rotate VERSALOK® inserter in a counterclockwise manner to remove inserter. Cut sutures and probe final repair.

TRIFECTA™
ROTATOR CUFF REPAIR SYSTEM

**PRODUCT DESCRIPTION****HEALIX Ti™ Anchor**

222253	4.5mm HEALIX Ti Anchor w/ORTHOCORD®
222245	5.5mm HEALIX Ti Anchor w/ORTHOCORD
222249	6.5mm HEALIX Ti Anchor w/ORTHOCORD
222242	5.5mm HEALIX Ti Anchor w/ORTHOCORD and Needles
222248	6.5mm HEALIX Ti Anchor w/ORTHOCORD and Needles
222271	4.5mm HEALIX Ti 3-Suture Anchor w/ORTHOCORD
222243	5.5mm HEALIX Ti 3-Suture Anchor w/ORTHOCORD
222241	6.5mm HEALIX Ti 3-Suture Anchor w/ORTHOCORD

HEALIX BR™ Anchor

222223	4.5mm HEALIX BR Anchor w/ORTHOCORD
222233	5.5mm HEALIX BR Anchor w/ORTHOCORD
222238	6.5mm HEALIX BR Anchor w/ORTHOCORD
222232	5.5mm HEALIX BR Anchor w/ORTHOCORD w/ Needles
222239	6.5mm HEALIX BR Anchor w/ORTHOCORD w/ Needles

HEALIX PEEK™ Anchor

222205	4.5mm HEALIX PEEK Anchor w/ORTHOCORD
222209	5.5mm HEALIX PEEK Anchor w/ORTHOCORD
222221	6.5mm HEALIX PEEK Anchor w/ORTHOCORD
222210	5.5mm HEALIX PEEK Anchor w/ORTHOCORD and Needles
222215	6.5mm HEALIX PEEK Anchor w/ORTHOCORD and Needles
222207	5.5mm HEALIX PEEK 3-Suture w/ORTHOCORD
222219	6.5mm HEALIX PEEK 3-Suture w/ORTHOCORD

HEALIX Instruments (For use with HEALIX BR & HEALIX PEEK)

222223	HEALIX Awl*
222226	4.5mm HEALIX Cortical Awl/Map*
222251	5.5mm HEALIX Cortical Awl/Map
222272	4.5mm HEALIX Full Awl/Map
222224	5.5mm HEALIX Full Awl/Map
222225	6.5mm HEALIX Full Awl/Map

*Cortical Awl is a trademark of Arthrex Inc. Naples FL

*Map is a registered trademark of Arthrex Inc. Naples FL

1. Data on file at DePuy Mitek, Inc.

2. Compared with Arthrex Coarsen IT Anchor.

3. Professor Pascal Boileau M.D. et al. The Mattress-Tens on-Bed (MTB) Technique: A Novel Arthroscopic Double-Row Anchor Cuff Repair.

4. Currents 2007 Arthroscopy & Athletic Injury, pp. 245, 2007 May.

5. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

6. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

7. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

PRODUCT DESCRIPTION**VERSALOK®**

210808	VERSALOK Anchor w/ ORTHOCORD
214710	Deployment Gun
214711	2.3mm Awl

EXPRESSEW® II Flexible Suture Passer

214004	EXPRESSEW II Device
214005	EXPRESSEW II Needles: Silver
270120	Grasper-Grabber Suture/Tendon Grabber

NEW Clear Cannula System

214106	5.5mm x 75mm Smooth
214114	7.0mm x 75mm Smooth
214107	5.5mm x 75mm Smooth with D stal Rib
214115	7.0mm x 75mm Smooth with D stal Rib
214104	5.5mm x 55mm Threaded
214118	8.5mm x 55mm Threaded
214108	5.5mm x 75mm Threaded
214116	7.0mm x 75mm Threaded
214120	8.5mm x 75mm Threaded
214110	5.5mm x 90mm Threaded
214122	8.5mm x 90mm Threaded

IDEAL™ Suture Shuttle with CHIA™

251001	IDEAL Suture Shuttle, 25° Left
251002	IDEAL Suture Shuttle, 25° Right
251003	IDEAL Suture Shuttle, 45° Left
251004	IDEAL Suture Shuttle, 45° Right
251005	IDEAL Suture Shuttle, 90° Up
251006	IDEAL Suture Shuttle, Straight Hook
251007	IDEAL Suture Shuttle, Straight Crescent

CHIA PERCASSER™

214101	CHIA PERCASSER Suture Passer
--------	------------------------------

8. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

9. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

10. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

11. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

12. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

13. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

14. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

15. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

16. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

17. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

18. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

19. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

20. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

21. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

22. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

23. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

24. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

25. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

26. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

27. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

28. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

29. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

30. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

31. Castagna A, Giarola R, Conti M, Borron M, Snyder S. Arthroscopic rotator cuff repair using a triple-loaded suture anchor and a modified Mason-Allen technique (Alex stitch). Arthroscopy. 2003;19:2, 2003 Apr.

32. Grosse A, Milano G, Labrousse M, Falciani M, Denel L, Fellegiani C, Singhewicz versus double-row arthroscopic rotator cuff repair: a prospective randomized clinical study. Arthroscopy. 2005;21:2, 2005 Jan.

33. Burke RT, Orr L, Green N, For R, Gray PE. A prospective randomized clinical trial comparing arthroscopic single and double-row rotator cuff repair: magnetic resonance imaging and early clinical evaluation. American Journal of Sports Medicine. 2003;31:442, 2003 Apr.

DePuy
Mitek Inc.

A Johnson & Johnson Company

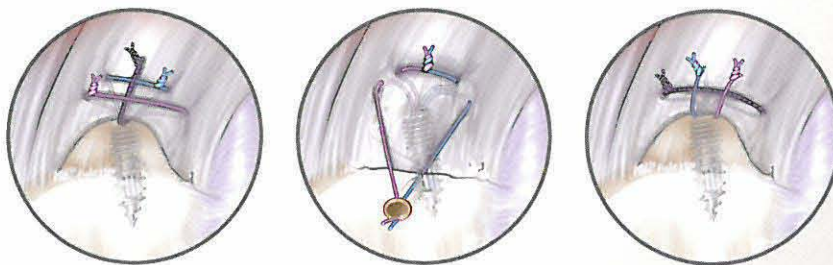


Dual Thread Suture Anchor with



2616 SOUTH LOOP WEST
SUITE 210, HOUSTON TX. 77054
PH: (713) 667-4780
FAX: (713) 667-4785

Optimized Fixation in Rotator Cuff Repair



never stop moving™



EXHIBIT “C”

BARNES & THORNBURG LLP

<http://www.btlaw.com>

1717 Pennsylvania Avenue, NW
Suite 500
Washington, DC 20006-4623

Switchboard: (202) 289-1313
Fax: (202) 289-1330
Direct Dial: (202) 408-6912
E-mail: joe.lewis@btlaw.com

Joseph D. Lewis

October 27, 2011

Mr. Scott Weiss
Senior Corporate Counsel
Healix Infusion Therapy, Inc.
4th Floor
14140 Southwest Freeway
Sugar Land, TX 77478

Re: Use of "HEALIX"
Our Ref.: 8629-46342

Dear Scott:

This is in response to your letter dated September 4, 2011, which you emailed to me over the Labor Day holiday weekend. Your letter asserts several purported violations of the Confidential Concurrent Use Agreement which you categorized with six exhibits. I will discuss each of these exhibits separately.

Exhibit A

This exhibit is an excerpt from the website of OrthoSport Surgical Inc. of Roseville, California. This company is an independent company which offers certain products of DePuy Mitek. Therefore, DePuy Mitek cannot control the website of this company in the same way that it controls its own website. In addition, as an independent third party, OrthoSport Surgical Inc. is not a party to the Agreement that exists between DePuy Mitek, Inc. and Healix Inc. and Healix Infusion Therapy, Inc.

Nevertheless, DePuy Mitek proceeded to review the matter with OrthoSport Surgical. OrthoSport Surgical had long ago been given the updated, current brochure for the HEALIX BR product. Indeed, the product listing page which you sent to us included a link to download a PDF version of the brochure for HEALIX BR. The brochure that was downloadable through that link was the current version and not the superseded 2008 version. Although the old brochure was discontinued, it appears that the logo in the form that appeared in the original brochure was retained on the company's product listing page, which is where you noted it. DePuy Mitek has been advised that this reference to the HEALIX BR product has been removed, and my own check of the website shows this to be the case.

Mr. Scott Weiss
October 27, 2011
Page 2 of 3

Exhibit B

This exhibit is the brochure for the HEALIX BR product that was updated after the settlement of the previous litigation had been concluded. This brochure has prominently been used over the last couple of years, and created in accordance with the mock up of changes to the original brochure that I forwarded to you on February 19, 2009, and which you confirmed would comply with the Concurrent Use Agreement. The word "Healix" is not being used as a stand alone mark in Exhibit B.

We note the reference in your letter to the exhibits to that Agreement. The exhibits depicting the stylized logo for HEALIX BR were included in the Agreement to illustrate forms of the logo which DePuy Mitek would be permitted to seek to register as a mark in the United States. Consequently, we do not believe that Exhibit "B" reflects any violation of the Agreement, or that any change to the material need be made.

Exhibit C

This exhibit is a marketing piece for the HEALIX Ti suture anchor. You have pointed to the use of "HEALIX" in the phrase "Engineered with HEALIX Dual Thread Technology™." We do not agree that this use is use of "HEALIX" as a stand-alone mark. In this marketing piece, the display of "HEALIX" to which you refer is part of the reference to "HEALIX Dual Thread Technology." Consequently, the display of "HEALIX" is display along with another term, as permitted by the Agreement. The trademark notice that appears with the phrase appears after the word "Technology" and is not adjacent to "HEALIX." The term "HEALIX" is not being used as a company name or the name of any operating division of DePuy Mitek. Therefore, this usage is compliant with the Concurrent Use Agreement.

Exhibit D

This exhibit is an excerpt from the website of Metro Surgical Solutions of Middletown, New Jersey. This company is an independent company which offers certain products of DePuy Mitek. Therefore, DePuy Mitek cannot control the website of this company in the same way that it controls its own website. In addition, as an independent third party, Metro Surgical Solutions is not a party to the Agreement that exists between DePuy Mitek, Inc. and Healix Inc. and Healix Infusion Therapy, Inc.

Nevertheless, DePuy Mitek proceeded to review the matter with Metro Surgical Solutions and has been advised that the material that was of concern to your company has been removed.

Mr. Scott Weiss
October 27, 2011
Page 3 of 3

Exhibit E

This exhibit contains a list of references to use of "HEALIX" on the Johnson & Johnson and/or DePuy websites. Several of the references to which you referred were not ordinary accessible marketing pages, but rather taxonomy pages relating to the indexing of the websites. However, inasmuch as you were able to access the information, DePuy Mitek has taken steps to remove the references which were the subject of your letter. I have confirmed their removal and was not able to find any of these webpages. Should you find of any of the references remaining, I trust that you will let me know.


Exhibit F

This exhibit is a listing of products. Although the HEALIX BR product was not listed, it was referenced in the description of another listed product. This page has been removed and redirected to the main page at depuy.com.

I am hopeful that the above information will put to rest the issues raised by your letter. Of course, should there be any remaining concerns, DePuy Mitek stands ready to continue its good faith efforts to settle the matter.

Very truly yours,

BARNES & THORNBURG LLP



Joseph D. Lewis

JDL/chb

EXHIBIT “D”

http://metrosurgicalsolutions.com/helix/8075_Healix_BR_Sales_Sheet.pdf - Windows Internet Explorer

http://metrosurgicalsolutions.com/helix/8075_Healix_BR_Sales_Sheet.pdf

File Edit Go To Favorites Help

Google Search More >> lgeorge Convert Select

Favorites 27 C.O.N.C.O.R Suggested Sites Web Slice Gallery

http://metrosurgicalsolutions.com/helix/8075_Healix_...

66.7% Collaborate Sign Find

HEALIXTM BR
BIOCRL RAPIDE

TECHNIQUE⁴

2. Group like colored suture limbs together and pass either anteriorly or posteriorly with EXPRESSEW[®] II Flexible Suture Passer.
3. Grasp and remove inner suture limbs (one violet and one blue) together and tie a secure knot outside the shoulder.
5. Place limbs into a VERSALOK[™] Suture Anchor. Insert VERSALOK Anchor into the bone and load deployment gun. Once sutures are tensioned deploy anchor.
6. Rotate VERSALOK inserter in a counterclockwise manner to remove inserter. Cut sutures and probe final repair.

17.00 x 11.00 in

Now with the leading U.S. biocomposite material¹.

start 19 A 4 I... 7 M... 15 M... 4 A... Aim... Mic... 9:15 AM

http://metrosurgicalsolutions.com/helix/08_10_01_HEALIX_BR_Invitro_White_Paper.pdf - Windows Internet Explorer

http://metrosurgicalsolutions.com/helix/08_10_01_HEALIX_BR_Invitro_White_Paper.pdf

File Edit Go To Favorites Help

Google HEALIX TM BR Anchor with ORTHOCORD® Suture Search More >> lgeorge Convert Select

Favorites 27 C.O.N.C.O.R Suggested Sites Web Slice Gallery

http://metrosurgicalsolutions.com/helix/08_10_01_HE...

102% Collaborate Sign Find

HEALIX™ BR Anchor with ORTHOCORD® Suture

Anchor In-Vitro Performance

DePuy Mitek, Inc. Research and Development

Introduction

The HEALIX Biocryl Rapide® (BR) Suture Anchor is a fully threaded bone anchor to be used predominantly for Rotator Cuff soft tissue repair to bone. The additional cortical thread exclusive to the HEALIX anchor has been designed to optimize bone contact in both cortical and cancellous layers of the humeral head.

Objective

To determine the axial pullout strength of the 5.5 HEALIX BR Anchor with #2 ORTHOCORD when placed in in-vitro solution at six week and twelve week time frames.

Materials and Methods

Done

Unknown Zone

start 21 A 4 L 7 M 15 M 4 A Aim... Mic... 9:17 AM

http://metrosurgicalsolutions.com/helix/HEALIXBRPeekSutureAbrasionWhitePaper.pdf

File Edit Go To Favorites Help

Google fdex Search More >> Sign In Convert Select

Favorites 27 C.O.N.C.O.R Suggested Sites Web Slice Gallery

http://metrosurgicalsolutions.com/helix/HEALIXBRPeekSutureAbrasionWhitePaper.pdf

Find: helix Previous Next Options

102% Collaborate Sign Find

HEALIX™ BR & HEALIX™ PEEK Anchor with ORTHOCORD® Suture Abrasion White Paper

DePuy Mitek, Inc. Research and Development

Introduction

The HEALIX PEEK & HEALIX BR Suture Anchors are fully threaded bone anchors to be used predominantly for Rotator Cuff soft tissue repair to bone. The additional cortical thread exclusive to the HEALIX anchors has been designed to optimize bone contact in both cortical and cancellous layers of the humeral head.

Objective

To determine the number of cycles needed to abrade the sutures of the triple loaded 5.5 HEALIX PEEK Anchor with #2 ORTHOCORD, double loaded 5.5 HEALIX BR Anchor with #2 ORTHOCORD, and the Arthrex 5.5mm Bio-Corkscrew FT* with #2 Fiberwire* suture.

Materials and Methods

A test medium of 10 pcf foam block with a 20 pcf foam block laminate was used. The anchors were inserted into foam using the appropriate instruments and to the correct depth indicator line per the instructions for use. The foam loaded with the anchors was submerged in a water bath. One end of the suture loop was attached to a servo-hydraulic tester, which applied a tensile force on the suture. The other end of the suture was attached to a five-pound weight. The suture was tested at .75 Hz with ½ inch amplitude. The middle of the three sutures on the 5.5 HEALIX anchor was tested. The suture was cycled until the suture failed. A total of five of the 5.5

Done Unknown Zone

start 7 Ad... 4 In... 9 Mi... 11 M... 4 Ad... AimAt... 2:19 PM

DePuy.com | LUPINE®trade; Loop Plus Anchor W/ #2 PANACRYL®reg; - Windows Internet Explorer

http://www.depuy.com/healthcare-professionals/product-details/lupinetrade-loop-plus-anchor-w-2-panacryl

File Edit View Favorites Tools Help

Google LUPINE™ Loop Plus Anchor W/ #2 PANACRYL® Search More >> lgeorge Convert Select

Favorites 27 C.O.N.C.O.R Suggested Sites Web Slice Gallery

DePuy.com | LUPINE®trade; Loop Plus Anchor W/ #2 ...

+ A A - | | | | Search DePuy.com search

DePuy never stop moving™ >> for patients >> for professionals >> about DePuy

find a product keyword All Specialties find


PROFESSIONALS products education & training for your patients

Healthcare Professionals / Products / LUPINE®trade; Loop Plus Anchor w/ #2 PANACRYL®reg;

products Browse our broad range of products and solutions in orthopaedics, spinal care, sports medicine and neuroscience.

LUPINE™ Loop Plus Anchor w/ #2 PANACRYL®

overview **faq**




category: Soft Tissue Repair/Arthroscopy
focuses: Rotator Cuff, Instability, Small Joint
product family: LUPINE™ Anchors

Q: What size Cannula does HEALIX fit down?
 A: The 4.5 & 5.5 HEALIX & instruments will fit down the New DePuy Mitek 5.5mm Cannulas. While the 6.5mm HEALIX will fit down the New DePuy Mitek 7 & 8.5mm Cannula

Q: Do I have to use an Awl/Tap?
 A: No. The awl/tap is recommended for hard bone. Ultimately it is your preference but it is recommended in hard bone. Your surgeon can use the awl/tap combo and then insert the anchor or use the awl and then the awl/tap in combination. It is not necessary to use the awl before the awl/tap combo; it is more a matter of surgeon preference than performance.

Q: Does the Awl need to go to the appropriate laser line i.e. 4.5mm laser

related products < >

 LUPINE™ Loop Plus Anchor w/ #2 ORTHOCORD®

LUPINE™ Loop Plus Anchor w/ #2 ORTHOCORD®
 >> learn more

See more products related to:

Internet 100%

start 28 A 4 I. 7 M 15 M 4 A. Aim... Mic... 9:21 AM



[overview](#)

[faq](#)



category: Soft Tissue Repair/Arthroscopy
 focuses: Rotator Cuff, Instability, Small Joint
 product family: LUPINE™ Anchors

Q: What size Cannula does **HEALIX** fit down?
 A: The 4.5 & 5.5 HEALIX & instruments will fit down the New DePuy Mitek 5.5mm Cannulas. While the 6.5mm HEALIX will fit down the New DePuy Mitek 7 & 8.5mm Cannula.
 Q: Do I have to use an Awl/Tap?
 A: No. The awl/tap is recommended for hard bone. Ultimately it is your preference but it is recommended in hard bone. Your surgeon can use the awl/tap combo and then insert the anchor or use the awl and then the awl/tap in combination. It is not necessary to use the awl before the awl/tap combo; it is more a matter of surgeon preference than performance.
 Q: Does the Awl need to go to the appropriate laser line i.e. 4.5mm laser line for HEALIX 4.5 and 5.5/6.5mm laser line for HEALIX 5.5 & HEALIX 6.5?
 A: Yes, cheating on awling increases the force to insert anchors and can cause distal breakage of the anchors. It is very import to instruct your surgeon on the proper insertion steps for **HEALIX**.
 Q: What does the vertical laser line on the inserter indicate?
 A: The vertical laser line on the inserter indicates the orientation the suture so that your surgeon can align his suture coming out of the anchor with the suture configuration they would like to use.
 Q: How long is the awl?
 A: The awl from distal tip to the 4.5 laser line is 22 mm in length. The awl from distal tip to the 5.5/6.5 laser line is 29 mm in length.
 Q: How big is the anchor?
 A: HEALIX 4.5 is 4.5mm in width and 18mm in length. HEALIX 5.5 is 5.5mm in width and 18mm in length. HEALIX 6.5 is 6.5mm in width and 18mm in length.
 Q: What if the **HEALIX** anchor needs to be removed?
 A: The **HEALIX** inserter can be easily placed back over the anchor and the anchor can be removed.

Additional product information:

Arthroscopic Bankart Repair Using Lupine Loop & BioKnotless
 Revision of the Lateral Epicondyle Using Mitek Stabilization
 90008.swf
 LUPINE™ LOOP ANCHOR SYSTEM
 LUPINE™ BR & BIOKNOTLESS™ BR
 Anchors...NOW with Biocryl Rapide.

related products



LUPINE™ Loop Plus
 Anchor w/ #2
 ORTHOCORD®

LUPINE™ Loop Plus Anchor w/ #2
 ORTHOCORD®
[learn more](#)

See more products related to:

Foot & Ankle
 Knee
 Shoulder & Elbow
 Soft Tissue Repair/Arthroscopy
 Rotator Cuff, Instability
 Small Joint

Search Foot & Ankle Products

keyword

[Find](#)

[back to search results](#)

Last updated on: Nov 25 2011 - 12:41:37